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Practitioner's Docket No. 1581/120

PATENT

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application

of Fotinos, S. et al.

Inventor(s)

for A DEVICE AND METHOD FOR THE TREATMENT OF ERECTILE DYSFUNCTION  
Title of Invention

OR

In re application of: Fotinos, S. et al.

Serial No.: 09/340,338

Group Art Unit: 1615

Filed: June 25, 1999

Examiner:

For: A DEVICE AND METHOD FOR THE TREATMENT OF ERECTILE DYSFUNCTION

Assistant Commissioner for Patents  
Washington, D.C. 20231TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT  
WITHIN THREE MONTHS OF FILING OR  
BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. 1.97(b))

NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant: (1) within three months of the filing date of a national application; (2) within three months of the date of entry of the national stage as set forth in § 1.491 in an international application; or (3) before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. 1.97(b).

## CERTIFICATE OF MAILING/TRANSMISSION (37 C.F.R. 1.8a)

I hereby certify that this correspondence is, on the date shown below, being:

## MAILING

☒ deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Date: 10/13/99

## FACSIMILE

☐ transmitted by facsimile to the Patent and Trademark Office.

Signature

Sonia K. Guterman, Ph.D.

(type or print name of person certifying)

NOTE: The "filing date of a national application" under 37 C.F.R. 1.97(b) has two possible meanings. Where the filing is a direct one to the United States Patent & Trademark Office, the filing is defined in 37 C.F.R. 1.53(b) as "the date on which: (1) A specification containing a description pursuant to § 1.71 and at least one claim pursuant to § 1.75; and (2) any drawing required by § 1.81(a), are filed in the Patent and Trademark Office in the name of the actual inventor or inventors as required by § 1.41." 37 C.F.R. 1.97(b)(1). On the other hand, an international application that enters the national stage occurs when the applicant has filed the documents and fees required by 35 U.S.C. § 371(c) within the periods set forth in § 1.494 or § 1.495. 35 U.S.C. § 371(c) requires the filing of the following: (1) the national fee; (2) a copy of the international application, unless already sent by the International Bureau, and an English translation if filed in another language; (3) amendments under PCT Article 19, with a translation into English if made in another language; (4) an oath or declaration; and (5) a translation into English of any annexes to the international preliminary examination report, if such annexes were made in another language. 37 C.F.R. 1.97(b)(2).

### IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING INFORMATION DISCLOSURE STATEMENT

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. 1.97(b).

NOTE: "No certification or fee is due when the filing is made within the above time period. It is advisable to ensure that no Office action has been mailed if the disclosure statement is delayed until after three months from filing."

NOTE: "An information disclosure statement will be considered to have been filed on the day it was received in the Office, or on an earlier date of a mailing if accompanied by a properly executed certificate of mailing under 37 C.F.R. 1.8, or Express Mail certificate under 37 C.F.R. 1.10. An Office action is mailed on the date indicated in the Office action." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "The term 'national application' includes continuing applications (continuations, divisions, continuations-in-part) so three-months will be measured from the actual filing date of an application as opposed [sic] to the effective date of a continuing application." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "An action on the merits means an action which treats the patentability of the claims in an application, as opposed to only formal or procedural requirements. An action on the merits would, for example, contain a rejection or indication of allowability of a claim or claims rather than just a restriction requirements (37 C.F.R. 1.142) or just a requirement for additional fees to have a claim considered (37 C.F.R. 1.16(d)). Thus, if an application was filed on Jan. 1 and the first Office action on the merits was not mailed until six months later on July 1, the examiner would be required to consider any proper information disclosure statement filed prior to July 1." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

WARNING: "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63).

  
SIGNATURE OF PRACTITIONER

Reg. No.: 44,729

Sonia K. Guterman, Ph.D.

Tel. No.: (617) 443-9292

(type or print name of practitioner)

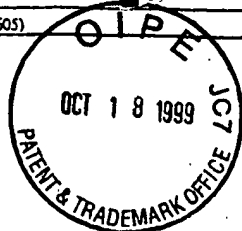
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BROMBERG & SUNSTEIN LLP

P.O. Address

125 Summer Street, Boston, MA 02110

(Transmittal of Information Disclosure Statement Within Three Months of Filing or Before Mailing of First Office  
Action [6-3]—page 2 of 2)



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**PATENT****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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Filed: June 25, 1999

Examiner:

For: A DEVICE AND METHOD FOR THE TREATMENT OF ERECTILE DYSFUNCTION

Assistant Commissioner for Patents  
Washington, D.C. 20231**INFORMATION DISCLOSURE STATEMENT****CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10***(When using Express Mail, the Express Mail label number is mandatory;  
Express Mail certification is optional.)*

I hereby certify that, on the date shown below, this correspondence is being:

**MAILING**☒ deposited with the United States Postal Service in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231

37 C.F.R. 1.8(a)

37 C.F.R. 1.10\*

☒ with sufficient postage as first class mail.☐ as "Express Mail Post Office to Addressee"

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**TRANSMISSION**☐ transmitted by facsimile to the Patent and Trademark Office.

Signature

Date: 10/13/99Sonia K. Guterman, Ph.D.

(type or print name of person certifying)

**\*WARNING:** Each paper or fee filed by Express Mail **must** have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).*"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.*(Information Disclosure Statement [6-1]—page 1 of 7)

NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant:

- (1) Within three months of the filing date of a national application;
- (2) Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application; or
- (3) Before the mailing date of a first Office action on the merits, whichever event occurs last."

37 C.F.R. 1.97(b).

NOTE: "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. 1.56(c).

NOTE: The "duty as described in § 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b) - (d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13 -25 at 17.

WARNING: "No information disclosure statement may be filed in a provisional application." 37 C.F.R. § 1.51(b).

### List of Sections Forming Part of This Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement: discard unused sections and number pages consecutively)

1. ☒ Preliminary Statements
2. ☒ FORM PTO-1449 (PTO/SB/08A and 086)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items
  - 7A. ☐ EPO Search Report
  - 7B. ☐ English Language Version of EPO Search Report
8. ☐ Translation(s) of Non-English Language Documents
9. ☐ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections \_\_\_\_\_, respectively, have been continued on ADDED PAGE(S).

NOTE: "Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

(Information Disclosure Statement [6-1]—page 2 of 7)

**Section 1. Preliminary statements**

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

**Section 6. Copies of Listed Information Items Accompanying This Statement**

NOTE: 37 C.F.R. 1.98(a)(2) requires that any information disclosure statement filed under § 1.97 shall include: "A legible copy of: (i) Each U.S. and foreign patent; (ii) Each publication or that portion which caused it to be listed; and (iii) All other information or that portion which caused it to be listed, except that no copy of a U.S. patent application need be included . . . "

NOTE: The wording in § 1.98(a)(2)(iii) makes it clear that the requirement to submit a copy of each item of information listed in an information disclosure statement does not apply to the citation of a U.S. patent application. Notice of January 9, 1992, 1135 O.G. 13-25, at 14.

Legible copies of all items listed in Form PTO-1449 (PTO/SB/08A and 08B) accompany this information statement.

*(complete the following, if applicable)*

- ☐ Exception(s) to above:
  - ☐ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.
  - ☐ Cumulative patents or publications identified in Section 5.

(Information Disclosure Statement—Section 6. Copies of Listed Information Items Accompanying  
This Statement [6-1]—page 6 of 7 )

**Section 10. Identification of Person(s) Making THIS INFORMATION DISCLOSURE STATEMENT**

The person making this statement is

*(check each applicable item)*

- (a) ☐ the inventor(s) who signs below

\_\_\_\_\_  
SIGNATURE OF INVENTOR

\_\_\_\_\_  
*(type name of inventor who is signing)*

- (b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. 1.56(c))

\_\_\_\_\_  
SIGNATURE OF INVENTOR

\_\_\_\_\_  
*(type name of inventor who is signing)*

- (c) ☒ the attorney who signs below on the basis of the information:

*(check each applicable item)*

- ☐ supplied by the inventor(s).  
☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. 1.56(c))  
☒ in the attorney's file.

Reg. No.: 44,729

Tel. No.: (617) 443-9292

Customer No.: 002101

Sonia K. Guterman  
SIGNATURE OF PRACTITIONER

Sonia K. Guterman, Ph.D.

\_\_\_\_\_  
*(type or print name of practitioner)*

BROMBERG & SUNSTEIN LLP

\_\_\_\_\_  
P.O. Address

125 Summer Street, Boston, MA 02110  
\_\_\_\_\_

(Information Disclosure Statement—Section 10. Identification of Person(s) Making This Information Disclosure Statement [6-1]—page 7 of 7)